Remarks

Claims 4-5, 7-9, 12-18, 20-31 and 44 are pending in this application. Claims 1, 2, 10, 11, and 43 are canceled without prejudice to Applicant's right to pursue the subject matter recited by them in one or more divisional, continuation and continuation-in-part applications. All of the pending claims are properly supported by the specification and claims as filed. No new matter has been introduced.

A. The Rejection Under 35 U.S.C. § 112 Should Be Withdrawn

On page 2 of Office Action, claims 1, 2, 4, 5, 7-18, 20-31, 43 and 44 are rejected under 35 U.S.C. § 112 first paragraph, as allegedly not enabled. Applicant respectfully disagrees with this rejection for the following reasons.

As the Examiner is aware, patents preferably omit what is well known in the art. Manual of Patent Examining Procedure ("M.P.E.P"), § 2164.01 (8th *ed.*, August 2001). Consequently, "the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *Id.* (quoting *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). Furthermore, experimentation is not "undue" simply because it may be complex, expensive, or time-consuming. *Id.*, §§ 2164.01 and 2164.06 (citing, *for example, In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); *In re Colianni*, 561 F.2d 220, 224 (CCPA 1977); *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988)).

In order to expedite the prosecution of this application and without conceding to the validity of the rejection under 35 U.S.C. § 112, first paragraph, Applicant has cancelled claims 1, 2, 10, 11, and 43. Further, in order to expedite the prosecution of this application and without conceding to the validity of the rejection under 35 U.S.C. § 112, first paragraph, Applicant has amended claims 17 and 18 to remove the word "preventing." The amendments made herein are made without prejudice to Applicant's rights to pursue subject matter related to the cancellations and amendments in one or more divisional, continuation, or continuation-in-part applications. Applicant respectfully submits that the amendments obviate the rejections relating to the "prevention" of certain disorders and/or to the "prophylactic efficacy" of selected compounds.

The Examiner alleges that "no guidance [has been] provided in the disclosure for administering an effective amount." (Page 3). Applicant respectfully

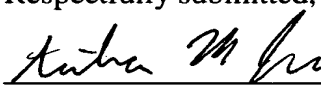
disagrees and submits that those of ordinary skill in the art can easily determine the effective amount of a compound of the invention. This determination is of the type regularly made by those of ordinary skill in the art. Indeed, the Board has long upheld this principle. For example, in *Ex Parte Skuballa*, 2 U.S.P.Q.2d 1570, 1571 (Bd. Pat. App. & Int., 1989), the Board held that a claim that required experimentation by those of ordinary skill in the art was not indefinite. The claim at issue in *Skuballa* recited the treatment of numerous disorders by administering "an effective amount of" a genus of compounds. *Id.* The examiner alleged, *inter alia*, that the use of the phrase "an effective amount of" rendered the claim indefinite. *Id.* The Board disagreed, and stated that its members "[were] satisfied that the skilled worker in this art could readily optimize effective dosages and administration regimens for each of the recited utilities." *Id.* (emphasis added).

Claims 4-5, 7-9, 12-18, 20-31 and 44 are directed, in part, to methods of treating atherosclerosis or inhibiting restenosis comprising administering "an effective amount" of a compound. Because compounds of this invention are clearly defined in the specification and claims, and because an effective amount can be readily determined in light of the specification as filed, the present claims, like the claims at issue in *Skuballa*, are enabled. Therefore, Applicant respectfully submits that the rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn.

No fee is believed due for this amendment. However, if a fee is due, please charge such fee to Jones Day Deposit Account No. 503013.

Respectfully submitted,

Date: July 6, 2004



35,203 (Reg. No.)

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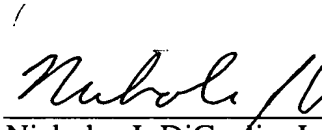

51,615 (Reg. No.)

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